K121505
Pg 1 of 2

COOK MEDICAL

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AUG 3 1 2012

5. 510(k) Summary

Name:	Wilson-Cook Medical, Inc. /Cook Endoscopy
Address:	4900 Bethania Station Road Winston-Salem, North Carolina 27105
Phone:	(336)744-0157
Fax:	(336)201-5994
Contact:	Scottie Fariole, Global Regulatory Affairs Specialist
Date:	May 18, 2012
Trade Name:	Disposable Hemostasis Clip
Common Name:	Hemostasis Clip
Classification Name:	Hemorrhoidal ligator, Gastroenterology-Urology (21 CFR 876.4400, Product Code MND)
Legally Marketed Devices:	Wilson-Cook Endoscopic Clipping Device (K023903)
Description of the Device:	The Disposable Hemostasis Clip is a sterile, single use device that consists of a metal clip that detaches from the introducer to maintain approximation of tissue to achieve hemostasis in the gastrointestinal tract. The device is compatible with endoscopes with a minimum accessory channel of 2.8 mm. The Disposable Hemostasis Clip is 230 cm long. The deployed clip portion of the Disposable Hemostasis Clip is stainless steel and nitinol while the introducer is nylon, stainless steel and nitinol.
Intended Use:	This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of endoscopic marking, hemostasis for mucosal/submucosal defects less than 3 cm in the upper GI tract, bleeding ulcers, arteries less than 2 mm, and polyps less than 1.5 cm in diameter in the GI tract. This device is not intended for the repair of GI tract lumenal perforations.
Technological Characteristics:	The Disposable Hemostasis Clip has similar technological characteristics to the Wilson-Cook Endoscopic Clipping Device (K023903) in terms of general design and function but differs in terms of materials, dimensions, clip geometry and handle operation. Additionally, the deployed clip portion of the device is MR Conditional per ASMT F2503.

Performance Data:	Performance testing consisting of non-clinical bench testing demonstrates that the Disposable Hemostasis Clip met the performance requirements to fulfill the intended use of the device. The device is substantially equivalent to currently cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

Wilson-Cook Medical, Inc. / Cook Endoscopy
Scottie Fariole
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K121505
Trade/Device Name: Disposable Hemostasis Clip
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): August 21, 2012
Received (Date on orig SE ltr): August 22, 2012

Dear Scottie Fariole,

This letter corrects our substantially equivalent letter of August 31, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K121505

Device Name: Disposable Hemostasis Clip

Indications for Use:

This device is used for endoscopic clip placement within the gastrointestinal tract for the purpose of endoscopic marking, hemostasis for mucosal/submucosal defects less than 3 cm in the upper GI tract, bleeding ulcers, arteries less than 2 mm, and polyps less than 1.5 cm in diameter in the GI tract. This device is not intended for the repair of GI tract lumenal perforations.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121505